

REMARKS

Claims 1-6, 9-11, and 32-36 are pending in the Application. Claims 1 and 11 have been amended. No new matter has been added. Claims 1 and 11 are independent.

On page 2 of the Office Action, Claims 1-6, 9-11 and 32-36 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Particularly, Page 3 of the Office Action states the specification fails to disclose “inflating an expandable membrane to a predetermined target pressure than [sic] exceeding the target pressure during ablation.” Applicant respectfully disagrees and points primarily to Paragraph [0052] of the Published Application (US 2005/0215989), which describes an inflation phase for inflating the expandable membrane. Paragraph [0052] states, “balloon 23 is inflated by injecting fluid or gas through the umbilical under a *fixed flow pressure*. This insures *a defined and constant pressure* inside the balloon in order to provide a mechanical force for inflation.” This “fixed...defined and constant” inflation pressure provides support for the “predetermined target pressure” stated in independent Claims 1 and 11.

Paragraph [0054] of the Published Application proceeds to disclose, “a pressure switch...monitors the pressure inside the balloon catheter 22. The solenoid valve 24 remains closed *until the pressure in the catheter is higher than the preset switch value* after which the solenoid valve opens to allow evacuation of excess refrigerant...During the transition, *ablation is already initiated but the pressure switch controls the balloon pressure until refrigerant flow alone maintains the balloon open.*” The disclosure of keeping the pressure above the preset

value supports the “exceeding the target pressure during ablation” of independent Claims 1 and 11.

Claims 1 and 11 have both been amended to recite a target pressure “lower than approximately 20 psi,” which Page 11 of the Office Action recognizes is supported.

Page 3 of the Office Action further states, regarding Claim 10, there is no disclosure of the steps being performed with an RF energy device. Applicant again respectfully disagrees. Paragraphs [0035] states, “If the user wishes to perform *an RF ablation procedure*, radiofrequency energy can be provided to electrodes on device 22 via electrical umbilical 16 to perform an RF ablation technique as is common in the art.” Paragraph [0041] states, “Console 20 is coupled to a catheter 22 via an umbilical system 12...and provides a return conduit for the coolant, electrical umbilical 16, *which transfers RF energy from console 20 to catheter 22 during an RF ablation procedure.*” These explicit disclosures directly support Claim 10’s “wherein the step of ablating the desired tissue region is part of a radio frequency ablation process.”

In view of the above, a withdrawal of the rejections under §112 is respectfully requested.

On page 4 of the Office Action, Claims 1-3, 9, 11 and 32-35 are rejected under 35 U.S.C. §102(b) as being anticipated by Joye et al. (US 6,428,534). In order to anticipate a claim, a reference must disclose each and every element of the claim.

Independent Claim 1 recites, in part, “controllably inflating the expandable membrane to at least *a predetermined target pressure*; ablating a desired tissue region, *wherein the pressure in the expandable membrane during ablation exceeds the target pressure.*” Independent Claim 11 similarly recites, in part, “the expandable membrane being inflated to a predetermined target

pressure” and “ablating the desired tissue region, wherein the pressure in the expandable membrane during ablation exceeds the target pressure.” Primarily, Joye fails to disclose inflating an expandable membrane to “a predetermined target pressure.” The Office Action cites to Col. 8, lines 5-20, which includes “the use of a feedback control system for initiating, regulating, and halting the supply of cryogenic fluid from fluid supply system 14.” But Joye’s general disclosure of a “control system” is not sufficient to anticipate inflation to “a predetermined target pressure,” or “ablating the desired tissue region, wherein the pressure in the expandable membrane during ablation exceeds the target pressure.” Indeed, Page 4 of the Office Action does not appear to indicate that Joye includes any such disclosure directed to the specific claimed methods of Claims 1 and 11. Instead, the Office Action refers generally to the above-cited feedback mechanism, which lacks any indication that the claimed methodology is included in the operation of Joye’s device.

Joye fails to disclose each and every element of independent Claims 1 and 11, and thus does not support the rejection under §102. A withdrawal of the rejection is therefore respectfully requested.

Dependent Claim 2 recites, in part, “keeping the expandable membrane inflated until a region proximate the expandable membrane reaches a predetermined temperature range,” while dependent Claim 32 recites “preventing deflation until a temperature in the balloon is higher than a predetermined temperature.” Joye fails to disclose this claimed methodology, and the Office Action does not point to any aspect of Joye that discloses such steps. The rejection is thus unsupported by the art, and a withdrawal is respectfully requested.

Claims 3, 9, and 33-35 recite additional limitations which, in conformity with the features of their corresponding independent claim, are not disclosed or suggested by the art of record. The dependent claims are therefore believed patentable.

On page 4 of the Office Action, Claims 4, 5 and 6 are rejected under 35 U.S.C. §103(a) as being unpatentable over Joye et al. ('534) in view of the teaching of Edwards (US 6,258,087). Claims 4, 5, and 6 are each dependent either directly or indirectly from independent Claim 1, discussed above. These claims recite additional limitations which, in conformity with the features of their corresponding independent claim, are not disclosed or suggested by the art of record. The dependent claims are therefore believed patentable. However, the individual reconsideration of the patentability of each claim on its own merits is respectfully requested.

On page 5 of the Office Action, Claim 10 is rejected under 35 U.S.C. §103(a) as being unpatentable over Joye et al.('534) in view of the teaching of Stern (US Patent No. 5,443,470). Claim 10 is dependent from independent Claim 1, discussed above. This claim recites additional limitations which, in conformity with the features of its corresponding independent claim, are not disclosed or suggested by the art of record. The dependent claim is therefore believed patentable. However, the individual reconsideration of the patentability of each claim on its own merits is respectfully requested.

On page 6 of the Office Action, Claims 3, 35 and 36 are rejected under 35 U.S.C. §103(a) as being unpatentable over Joye et al. ('534) in view of the teaching of Joye et al. (US 2002/0045894). Claims 3, 35 and 36 are each dependent either directly or indirectly from independent Claim 1, discussed above. These claims recite additional limitations which, in conformity with the features of their corresponding independent claim, are not disclosed or

suggested by the art of record. The dependent claims are therefore believed patentable.

However, the individual reconsideration of the patentability of each claim on its own merits is respectfully requested.

On page 6 of the Office Action, Claims 1-3, 9, 11 and 32-35 are rejected under 35 U.S.C. §103(a) as being unpatentable over Droegemueller (US Patent No. 3,924,628) in view of the teaching of Joye et al. ('534).

Independent Claims 1 and 11 state, “controllably inflating the expandable membrane to at least a *predetermined target pressure*,” and “ablating a desired tissue region, wherein the pressure in the expandable membrane during ablation *exceeds the target pressure*.” As described in Applicant’s previous response, Droegemueller discloses a bladder contacting the uterus, where the pressure of the bladder “should preferably be *maintained* at or about 2 or 3 p.s.i. to avoid any possible risk of injury to the patient,”(Col. 3:58-62)(emphasis added). This sole reference to bladder pressure explicitly recites *maintaining* a pressure, and makes no mention of exceeding that pressure whatsoever. Maintaining a single bladder pressure during operation is not “controllably inflating the expandable membrane to at least a *predetermined target pressure*,” and “ablating a desired tissue region, wherein the pressure in the expandable membrane during ablation *exceeds the target pressure*,” as stated in Applicants’ Claims 1 and 11. As discussed above, the Joye ‘534 reference also fails to disclose the claimed methodology.

Accordingly, Droegemueller and Joye, whether considered alone or in combination, fail to disclose “controllably inflating the expandable membrane to at least a *predetermined target pressure*,” and “ablating a desired tissue region, wherein the pressure in the expandable membrane during ablation *exceeds the target pressure*.” The rejection of Claims 1 and 11 is

thus unsupported, and a withdrawal of the rejection is respectfully requested. Dependent Claims 2-3, 9 and 32-35 are also believed allowable as they depend from independent Claims 1 and 11.

On page 7 of the Office Action, Claims 4, 5 and 6 are rejected under 35 U.S.C. §103(a) as being unpatentable over Droegemueller ('628) and Joye et al. ('534) and further in view of the teaching of Edwards (US Patent No. 6,258,087). Claims 4, 5, and 6 are each dependent either directly or indirectly from independent Claim 1, discussed above. These claims recite additional limitations which, in conformity with the features of their corresponding independent claim, are not disclosed or suggested by the art of record, and are therefore believed patentable.

On page 8 of the Office Action, Claim 10 is rejected under 35 U.S.C. §103(a) as being unpatentable over Droegemueller ('628) and Joye et al. ('534) in view of the teaching of Stern (US Patent No. 5,443,470). Claim 10 is dependent from independent Claim 1, discussed above. This claim recites additional limitations which, in conformity with the features of its corresponding independent claim, are not disclosed or suggested by the art of record, and is therefore believed patentable.

On page 9 of the Office Action, Claims 3, 35 and 36 are rejected under 35 U.S.C. §103(a) as being unpatentable over Droegemueller ('628) and Joye et al. ('534) and further in view of the teaching of Joye et al. (US 2002/0045894). Claims 3, 35 and 36 are each dependent either directly or indirectly from independent Claim 1, discussed above. These claims recite additional limitations which, in conformity with the features of their corresponding independent claim, are not disclosed or suggested by the art of record, and are therefore believed patentable.

For all of the above reasons, the claim objections are believed to have been overcome placing Claims 1-6, 9-11, and 32-36 in condition for allowance, and reconsideration and allowance thereof is respectfully requested.

The Examiner is encouraged to telephone the undersigned to discuss any matter that would expedite allowance of the present application.

The Commissioner is hereby authorized to credit overpayments or charge payment of any additional fees associated with this communication to Deposit Account No. 502104.

Respectfully submitted,

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By: /John Christopher/
John Christopher
Reg. No.: 37,596
Attorney for Applicant(s)
Christopher & Weisberg, P.A.
200 East Las Olas Boulevard, Suite 2040
Fort Lauderdale, Florida 33301
Customer No. 31292
Tel: (954) 828-1488
Fax: (954) 828-9122
email: ptomail@cwiplaw.com

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